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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,014	12/04/2001	Chen Xing Su	10209.276	6898

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KIRTON AND MCCONKIE
60 EAST SOUTH TEMPLE,
SUITE 1800
SALT LAKE CITY, UT 84111

EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/006,014	SU ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-10, 12, and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the declaration submitted by Claude Jarakae Jensen on 1/9/08. In addition, the Examiner acknowledges receipt of the amendment filed 1/9/08 wherein claims 1, 9, and 12 were amended and claims 2, 11, and 14 were canceled.

Note: Claims 1, 3-10, 12, and 13 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENTS

2. The Applicant's arguments and/or amendment filed 1/9/08 to the rejection of the claims made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 First Paragraph Rejection

The 112 first paragraph rejection is MOOT in light of the new grounds of rejection below.

103 Rejection

The 103 rejection is MOOT in light of the new grounds of rejection below.

NEW GROUNDS OF REJECTIONS

New Matter & Written Description Rejections

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3-10, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims contain new matter and lacks written description because the claims contain the phrase 'Morinda citrifolia juice is present in an amount of 2.31 percent by ***volume***'. In particular, the specification discloses that the biochemical assay results show that at a ***concentration*** of 2.31%, inhibition of COX-1 was noted (see specification, page 15, lines 1-2). Furthermore, the pending claims read on a volume percent of 2.31 while the specification reads on a concentration percent of 2.31. A volume percent is not the same as concentration percent. A percent volume is based on the total volume of the solution and the specific volume of the component of interest. However, a percentage based on concentration is dependent on the *mass and volume* of a material, not the volume alone. Hence, the claims contain new matter and the specification lacks written description as to the phrase 'percent by volume'.

The claim lacks written description because the term 'inhibits/inhibiting' COX-1 and COX-2 is not describe in such a way to convey to the reader that Applicant had possession of the invention at the time of filing. In particular, the term 'inhibit' reads on the preventing of COX-1 and COX-2 in the methods of the instant invention. Furthermore, the specification does not set forth how Applicant goes about guaranteeing that COX-2 and/or COX-1 is inhibited completely or to a desired amount.

Enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 9, 10, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to methods of treating pain and inflammation by administering 2.31 percent by volume of Morinda citrifolia juice. Review of the specification appears to indicate that due to some mode of action, somehow a patient experiencing pain and inflammation when administered Morinda citrifolia juice results in the treatment of the pain and inflammation.

(2) State of the prior art

The state of the prior art is that it is difficult to treat all kinds of pain and inflammation with a single compound/composition. For example, the pain and inflammation may be that associated with cancer since according to Hallahan (US Patent No. 6,159,443, column 22, lines 9-20), inflammatory condition include those that are immune and non-immune related. Possible conditions include rheumatism, psoriasis, diabetic retinopathy, neovascular glaucoma, atherosclerotic plaques and osteoporosis, as well as conditions such as cancer. A condition such as cancer remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known (see Golub et al., Science, October 15, 1999, pp. 531-537) that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types in order to maximize efficacy and minimize toxicity. The classification of cancer has been based primarily on morphological appearance of the tumor and that of tumors with similar histopathological appearance may follow significantly different clinical courses and have different responses to therapy (see Golub et al., Science, October 15, 1999, pp. 531-537). As a result, there is no absolute predictability of which tumors are treatable, even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the knowledge in the art would hinder one of ordinary skill in the art from accepting any therapeutic regimen as being acceptable for all tumor/cancer treatments. Additionally, for example, infection is a process that can take place in virtually any part of the body. Thus, there is a vast

range of infectious diseases that may occur based on the various biochemical pathways.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. There is no evidence of record which would enable the skilled artisan in the identification of the patients who have the potential of becoming afflicted with the numerous diseases or disorders that involve pain and inflammation which are encompassed by the instant invention. The assumption that the administering of Morinda citrifolia juice to treat all diseases/conditions wherein pain and inflammation is present is an incredible finding for which Applicants have not provided supporting evidence. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the specific diseases/conditions wherein pain and inflammation are effectively treated.

(4) Level of predictability in the art

The art pertaining to the treatment of pain and inflammation is highly unpredictable. Determining the various types or classes of diseases/conditions involving pain and inflammation which are treatable with the instant invention requires various experimental procedures and without guidance that is applicable to all pain and inflammation relating to diseases/conditions, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

There is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the

numerous diseases/conditions wherein pain and inflammation are treated effectively as claimed herein. While the specification does disclose Example 2 wherein it discloses that pain and inflammation is treated in a patient with infection, it does not set forth the type of location of the infection or the disease/condition for which the infection is present. In Applicant's Example 3, it is disclosed that pain, not inflammation, in a subject suffering from arthritis is treated. In Example 4, it is disclosed that a subject that *believes* that they are susceptible to a condition that results in chronic inflammation is being treated. However, the Example does not set forth what condition or the type of inflammation being treated. Furthermore, the example fails to confirm that the subject actually has an inflammation, but states that the subject suspects that they have a condition that will result in a chronic inflammation. In Example 6, it is disclosed that a subject is suffering from pain related to inflammation. It is unclear if the administering of the juice treats the pain or if the inflammation is actually treated as well. In Example 7, a subject is experiencing lower back and neck pain. The subject is administered the Morinda citrifolia juice to treat the pain, not inflammation associated with the lower back and neck pain. In Example 8, a subject is administered Morinda citrifolia to treat pain, not the inflammation, associated with muscle strains and sprains. Hence, based on Applicant's disclosure the limited guidance as it relates to the condition/disease being treated for pain and/or inflammation does not enable the public to prepare the desired Morinda citrifolia mixture for the treatment of pain and inflammation. In the provisionally application a specific amount of Morinda citrifolia was administered to a subject whereas in order to obtain desired results. However, in the instant application and

examples, there is no disclosure of the amount of Morinda citrifolia administered to a subject in order to treat the conditions/diseases set forth in the examples. Furthermore, due to the unlimited number of diseases/conditions that result in pain and/or inflammation and the fact that dosage ranges are not set forth, there is no directional guidance for the types or classes of diseases/conditions involving pain and/or inflammation that are treatable with Morinda citrifolia. Hence, there is no enablement for all possible diseases/conditions and pain and/or inflammation treatable with the claimed Morinda citrifolia juice and/or pulp.

(6) Existence of working examples

The instant invention encompasses a vast number of diseases/conditions that involve pain and/or inflammation. Applicant's limited working examples do not enable the public to prepare and use such a numerous amount Morinda citrifolia mixtures and treat a vast number of diseases/conditions having pain and/or inflammation.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible diseases/conditions known to exist that are associated with pain and/or inflammation. For example, there are many classes of diseases such as allogeneic, communicable, congenital, contagious, deficiency, endemic, functional, hereditary, infectious, local, occupational, organic, periodic, social, systemic, and venereal diseases that are known to affect a subject resulting in pain and/or inflammation.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 Second Paragraph Rejections

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3-10, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3-10, 12, and 13: The claims are ambiguous because in some of the claim (e.g., independent claims 1 and 9), it is disclosed that the Morinda citrifolia is a juice, but in some of the dependent claims, the material is a food product. The phrase 'food product' includes both liquids and solids. Furthermore, in dependent claim 3 for example, it is disclosed that the Morinda citrifolia is in liquid form. In independent claim 5, for example, it is disclosed that the Morinda citrifolia is in capsule form. Hence, it is unclear exactly what form of Morinda citrifolia Applicant is claiming in the independent claims.

Claims 9, 10, 12, and 13: The claims as written are ambiguous because it is unclear if Applicant is treating both the pain and inflammation associated with a

condition (i.e., a toothache) or if Applicant is treating the pain OR inflammation broadly. For example, in Applicant's Example 2, pain and inflammation are treated for an infection. In Example 3, pain and inflammation is treated for arthritis'. In Example 4 a person that believes they are susceptible to a condition that results in chronic inflammation is being treated. However, for Example 4, it is unclear what the condition is. It appears that a perceived 'pain and inflammation' is being treated which has not actually been identified.

Claims 1 and 3-8: The claim as written is ambiguous because it is unclear how Applicant is interpreting the term 'inhibiting'. The Examiner reviewed Applicant's specification for the term 'inhibit' and a definition thereof. However, a definition of such term was not found in the disclosure. Thus, the term 'inhibit' was given its broadest interpretation as set forth in any standard dictionary (i.e., Webster's Dictionary). The term 'inhibit' encompasses 'prevention' since a definition was not set forth by Applicant in the disclosure. According to the standard dictionary (i.e., Webster's Dictionary, New Riverside University Dictionary, 1984, page 629), the term 'inhibit' is defined as 'to restrict or hold back'; 'restrain'; 'to prohibit'; or 'forbid'. Furthermore, according to the standard dictionary (i.e., Webster's Dictionary), the term 'forbid' means 'to command one not to do something or prohibit'. The term 'prohibit' means 'to forbid by authority or to ***prevent***'. Thus, the term 'inhibit' in the claims does not exclude the claims from the concept that the method (and/or compound/composition) reads on prevention.

103 Rejection

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 3-10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (US Patent No. 7,070,813) in view of Hallahan (US Patent No. 6,159,443) in further view of Gidlund (US Patent No. 6,436,449).

Jensen et al disclose the preventive and treatment effects of Morinda citrifolia as a colon cancer cell growth inhibitor (see entire document, especially abstract). The Morinda citrifolia may be in the form of a juice, puree, pulp, oil, or dietary fiber (column 3, lines 38-41). Morinda citrifolia is thought to possibly inhibit cancer cell growth within the colon (column 3, lines 47-52). There are many benefits of Morinda citrifolia. The substance may be administered to persons to aid in treatment of cancer, arthritis, headaches, indigestion, malignancies, broken bones, high blood pressure, diabetes, pain, infection, asthma, toothaches, blemishes, immune system failure, and various other conditions (columns 7-8, bridging paragraph). The compositions containing Morinda citrifolia may be administered orally (column 8, lines 4-23). In addition, Jensen et al disclose that Morinda citrifolia products have COX-1 and COX-2 implications. COX-1 is the constitutive and is used to synthesize protective prostaglandins to line stomach and maintain normal renal function. COX-2 is inducible and induced at infected sites by those associated with inflammation. Thus, it is known in the art that COX-1 is needed and COX-2 is desirably inhibited (column 12, lines 36-49). The studies of Jensen et al disclose that Morinda citrifolia products were able to inhibit COX-2 resulting in the decrease of prostaglandin production and increased apoptosis (column 12, lines 50-62). The results of Jensen et al indicated that Morinda citrifolia exhibited significant growth inhibition (greater than 50%) relative to the respective

vehicle treated control group at a concentration between 2-10% (see column 13, lines 7-11; column 14, Table 1-1). However, while Jensen et al disclose that Morinda citrifolia had significant growth inhibition in the range of 2-10%, the document fails to exemplify 2.31 as the critical percent concentration value.

Hallahan discloses that the phrase 'inflammatory condition' include those that are immune and non-immune related. Possible conditions include rheumatism, psoriasis, diabetic retinopathy, neovascular glaucoma, atherosclerotic plaques and osteoporosis, as well as conditions such as cancer (see column 22, lines 9-20).

Gidlund discloses a composition comprising Morinda citrifolia that may be in liquid or solid form (see entire document, especially, abstract; column 4, lines 26-30). In particular, this document is cited because in the background of the invention, it is disclosed that the active ingredient has medicinal uses for physical conditions such as high blood pressure, menstrual cramps, arthritis, gastric ulcers, sprains, injuries, mental depression, senility, poor digestion, atherosclerosis, blood vessel problems, drug addiction, and pain (column 2, lines 15-19). In addition, Gidlund discloses that the medicament when administered orally may be a liquid solution, emulsion, capsule, or tablet (column 5, lines 56-62).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Jensen et al using the teachings of Gidlund and generate a method of selectively inhibiting COX-2 relative to COX-1 by administering 2.31% concentration of Morinda citrifolia juice for the reasons set forth below. Likewise, it would have been obvious to one at the time the invention was made

to administer 2.31% concentration of Morinda citrifolia juice to treat pain and inflammation as set forth below.

Jensen et al disclose that Morinda citrifolia juice may be used in the liquid form in the treatment of pain and inflammation and for inhibiting COX-2 relative to COX-1. Specifically, review of Table 1-1, column 14 (see also column 13, lines 7-11) disclose the concentrations of test compound used for growth inhibition relative to control groups at various concentration percentages of Morinda citrifolia. While Jensen et al does not specifically state in the disclosure that the critical percent concentration is 2.31, in Table 1-1 a skilled artisan would recognize that would recognize that Morinda citrifolia exhibited significant growth inhibition (>50) relative to the treated control group at a concentration range between 2% and 10%. Thus, Applicant is reminded that the optimization within prior art conditions or through routine experimentation is within the skill of an artisan when the general conditions of a claim are disclosed in the prior art (*In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)). In addition, Applicant is reminded that generally differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. The Examiner recognizes that a parameter must first be recognized as a result-effective variable (i.e., a variable which achieves a recognized result) before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation (*In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)). In the cited prior art, the

significance of the percent concentration of the Morinda citrifolia juice was recognized (see column 13, lines 7-11; column 14, Table 1-1).

It should be noted that Hallahan is cited because it discloses that the term 'inflammation' encompasses cancer. Thus, since cancer is known as a type of inflammatory condition, the skilled artisan would recognize that the Jensen et al document cited above is useful for treating inflammation.

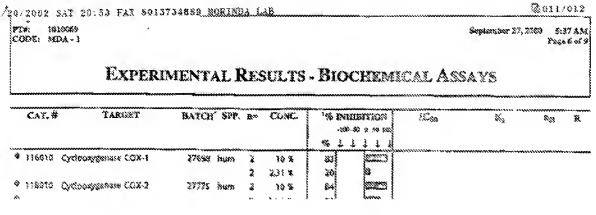
It should be noted that Gidlund is cited because the document discloses that it is well known in the art to use Morinda citrifolia in the treatment of various conditions involving pain and inflammation. Furthermore, since Jensen et al and Gidlund are both directed to the use of Morinda citrifolia for medicinal purposes (i.e., in the treatment of pain and inflammation), the references may be considered to be within the same field of endeavor. Thus, the reference teachings are combinable.

COMMENTS/NOTES

13. It is duly noted that Applicant is claiming benefit to provisional application 60/251,416 filed 12/5/00. However, Applicant is not entitled to the filing date of the provisional application set forth below. First, it should be noted that the full disclosure of the provisional application is set forth below.

COX-1 and COX-2 Inhibition Study on TNJ

Summary: TNJ was test for COX-1 and COX-2 inhibition. Laboratory result Showed that at 3 OZ per day, the inhibition of COX-2 was 58% and The inhibition of COX-1 was 20%.



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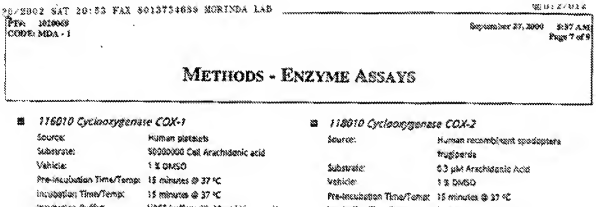
Page 6 of 9

EXPERIMENTAL RESULTS - BIOCHEMICAL ASSAYS

CAT. #	TARGET	BATCH	SPP.	n=	CONC.	% INHIBITION -100 -50 0 50 100	IC_{50}	S_D	S_{EM}	R
116010	Cyclooxygenase COX-1	27658	hum	2	10 %	58				
				2	2.31 %	20				
118010	Cyclooxygenase COX-2	27771	hum	2	10 %	84				



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CODE: MDA - 1

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Page 7 of 9

METHODS - ENZYME ASSAYS

■ *116010 Cyclooxygenase COX-1*

Source:	Human platelets
Substrate:	50000000 Cell Arachidonic acid
Vehicle:	1 % DMSO
Pre-Incubation Time/Temp:	15 minutes @ 37 °C
Incubation Time/Temp:	15 minutes @ 37 °C
Incubation Buffer:	HBSS buffer with 15mM Hepes, pH 7.4
Quantitation Method:	EIA quantitation of PGE_2
Significance Criteria:	≥ 50% of max stimulation or inhibition

■ *118010 Cyclooxygenase COX-2*

Source:	Human recombinant spodoptera frugiperda
Substrate:	0.3 µM Arachidonic Acid
Vehicle:	1 % DMSO
Pre-Incubation Time/Temp:	15 minutes @ 37 °C
Incubation Time/Temp:	5 minutes @ 37 °C
Incubation Buffer:	100 mM Tris-HCl, 1 mM glutathione, 1uM hematin ,500 µM phenol, pH 7.7
Quantitation Method:	EIA quantitation of PGE_2
Significance Criteria:	≥ 50% of max stimulation or

The information of the provisional is specifically directed to the testing of TNJ for COX-1 and COX-2 inhibition. The results specifically state that based on the laboratory result, 3 ounces per day (the Examiner assumes that Applicant is administering TNJ which is assumed to be Tahitian noni juice) to a subject. The administration of 3 ounces per day resulted in the inhibition of COX-2 at 58% and the inhibition of COX-1 at 20%. Thus, since the pending claims do not contain the specific limitations as set forth in the

provisional application, the instant invention is not entitled to the filing date of the provisional application. The instant claims read on a method of selectively inhibiting COX-2 relative to COX-1 by administering Morinda citrifolia juice in an amount of 2.31 percent by volume. In addition, the instant invention contains claims directed to methods of treating pain and inflammation which were not disclosed in the provisional application.

14. It is duly noted that Applicant submitted a declaration by Claude Jarakae Jensen on 1/9/08. The declaration has been reviewed but found non-persuasive because (1) it refers to research described in attached documentation that is not present in the application and (2) the remaining portions of the declaration are opinion oriented.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/

D. L. Jones
Primary Examiner
Art Unit 1618

April 28, 2008